WSA 2001 Proposed Project Plan

Project Name: Total Exposure Study in US #1148

Objective: Measure the uptake of selected vapor phase and particulate smoke components for an appropriate U. S. population based on suitable biomarker(s).

Deliverable(s): Report and publication

Need Addressed: Providing a baseline for future cigarette-design related studies by 2002.

Plan Area (select one): Understanding S&H ☒ Communication ☐ Acceptance ☐ Harm Reduction ☒

Disease (select one): Cancer ☐ CVD ☐ COPD ☐ Repro ☐ All ☐ Other ☒ (specify) benchmark of exposure

Project Leader: Roger Walk

Tactics and Milestones:	Target Date:
For 2001	
Complete contracts with CRO for:	
• (1) Method development and repeatability testing, questionnaire development, data analysis plan	(1) December 22, 2000
• (2) Pilot study	(2) January 31, 2001
Establish:	
• (3) SRB	(3) February 16, 2001
• (4) Consultants	(4) March 30, 2001
Method development and repeatability testing, questionnaire and data analysis plan development	
• (5) Start	(5) January 8, 2001
• (6) Complete	(6) May 31, 2001
(7) Publication of study design	(7) July, 2001
Pilot study	
• (8) Approved protocol	(8) July, 2001
• (9) Complete Recruiting and Screening of volunteers	(9) September, 2001
• (10) Complete Clinical Study Report	(10) December, 2001
• (11) Complete Biomarker Report	(11) March, 2002

CRITICAL RESOURCE ALLOCATION

Internal Resources (WSA, INBIFO)	External Resources (other PMUSA, external vendors)
Robin Kinser (25%); T. Tricker (5%); B. Nelson (40%); G. Schepers (<5%); H.-J. Hausmann (<5%);. K. Rustemeier (5%); W. Gomm (5%); R. Walk (30%); T. Sanders (<5%); W. Reininghaus (<5%); K. von Holt (5%); J. Oey (35%)	D. Leyden, R. Carchman, R. Rylander, J. Gear, C. Adams, D. Compton, D. Sica, C. Gennings, SRB, Contract Laboratory--$1,350,000

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